NOV 1 6 2000 K001663

medrad®

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name:	Medrad Inc.
Submitter's Address:	One Medrad Drive, Indianola, PA 15051 USA
Telephone Number:	(412) 767-2400, ext. 3536
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Contact Person:	Frank Pelc
Date:	May 30, 2000
Proprietary Name:	Front-load Polypropylene Syringe
Common Name:	Syringe, Angiographic
Classification:	74DXT
Classification Name:	Injector and Syringe, Angiographic
Predicate Device:	Liebel-Flarsheim (LF) 200 ML Syringe for CT 9000 (K902221)

Medrad, Inc.
One Medrad Drive
Indianola, PA 15051-0780
(412) 767-2400

Substantial Equivalence - The Front-load Polypropylene Syringe is substantially equivalent to the LF 200 ML Syringe for CT 9000 (K902221). Both products have the same intended use to deliver contrast media. Both are indicated for single-use on the LF CT 9000 Injector. Both have 200 ML capacity.

A table comparing the features and principles of operation between the proposed device and predicate device is provided in the table below. The Medrad Front-Load Syringe (K924116, K964642) which is made with a non-polypropylene barrel, is also provided for comparison.

COMPARISON DATA

	Proposed Device: Front-load Polypropylene Syringe	**Predicate Device:** LF 200 ml syringe for the LF CT 9000 Injector (K902221)	**Medrad Front-Load Syringe** (K924116, K964642) (Made of non-polyprop. material; provided for comparison purposes)
Intended Use	For delivery of contrast media with the LF CT 9000 injector	For delivery of contrast media with the LF CT 9000 injector.	For delivery of contrast media with Medrad injectors
Single Use	Yes	Yes	Yes
Sterility	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)
Shelf Life	1 Year (The syringe will be extended to 5-year shelf life when satisfactory test results are completed.)	5 Years	5 Years
Volume	200 ml	200 ml	200 ml
Pressure Capabilities to CT 9000's 300 psi maximum	Yes	Yes	N/A (This syringe is not used with the CT 9000)

Quality for Life

COMPARISON DATA (Continued)

	Proposed Device: Front-load Polypropylene Syringe	**Predicate Device:** LF 200 ml syringe for the LF CT 9000 Injector (K902221)	**Medrad Front-Load Syringe** (K924116, K964642) (Made of non-polyprop. material; provided for comparison purposes)
Interface with Injector	Syringe twists onto turret adapter which is attached to the LF injector. No pressure jacket.	Pressure jacket attaches to removable turret which is attached to LF injector, and syringe fits inside pressure jacket.	Syringe twists onto Medrad injector. No pressure jacket.

Test Information - Testing performed on the Front-load Polypropylene Syringe proves that the product is substantially equivalent to the LF 200 ml syringe when used on the LF CT 9000 injector. The testing includes the syringe, turret adapter, and heater adapter used on the LF CT 9000 injector. Included was testing to verify that use of the product would not affect or compromise the base product's capability to meet the requirements of UL544, CSA 125, IEC 601-1, or IEC 601-1-2. Also included are tests on Medrad's new barrel material per AAMI/ANSI ISO guidance for the biomedical evaluation of Medical Devices-10993-1: 1994, Part 1. The testing shows that the product met all of the design requirements stated in its product specification.

Device Description - The proposed Medrad Front-load Polypropylene Syringe consists of a 200 ml Front-load Syringe, turret adapter, and heater adapter, for use on the LF 9000 CT Injector. The syringe consists of a non-pressure jacketed front load syringe barrel, a plastic plunger, and an elastomeric seal covering the plunger. Fluid is drawn into or expelled from the syringe by its plunger, which is powered and controlled by the CT 9000 injector.

Intended Use - The Front-load Polypropylene Syringe is indicated for the delivery of contrast media. The syringe is indicated for single-use only with the LF CT 9000 injector.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2000

Mr. Frank W. Pelc III
Regulatory Affairs Coordinator
Medrad Inc.
One Medrad Drive
Indianola, PA 15051

Re: K001663
Trade Name: Front-Load Polypropylene Syringe
Regulatory Class: II (two)
Product Code: DXT
Dated: September 8, 2000
Received: September 11, 2000

Dear Mr. Pelc:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number:_____

Device Name: Front-load Polypropylene Syringe

Indications for Use/Intended Use:

The Front-load Polypropylene Syringe is indicated for the delivery of contrast media. The syringe is indicated for single-use only with the LF CT 9000 injector.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001663

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)